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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,341	08/25/2005	Katsutoshi Sasaki	BJS-4093-8	3748

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EXAMINER	
VOGEL, NANCY TREPTOW	
ART UNIT	PAPER NUMBER
1636	
MAIL DATE	DELIVERY MODE
03/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,341	SASAKI ET AL.	
	Examiner	Art Unit	
	NANCY VOGEL	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75,77 and 109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75, 77, 109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/5/09 has been entered.

Claims 75, 77 and 109 are pending in the case.

The following is a new rejection necessitated by applicant's amendments:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 77 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 77 is vague and indefinite in the recitation of "a DNA encoding Gα protein of a chimeric Gα protein" since it is not clear what is intended by this phrase. It has been assumed for examination purposes that "a DNA encoding Gα protein or a chimeric Gα protein" is intended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 77 rejected under 35 U.S.C. 103(a) as being unpatentable over Braselmann et al. . (Proc. Natl. Acad. Sci. USA 90:1657-1661, 1993) in view of Miyaji et al. (Cytotechnology, 4(2):173-180, 1990), and Scheirer (US Patent 5,866,342).

Braselmann et al. disclose a mammalian cell comprising a DNA construct for expression of a transcription factor necessary for construction of an inducible expression system, wherein the transcription factor is a chimeric protein of a ligand binding domain of estrogen receptor and yeast Gal4p. Braselmann et al. disclose cells comprising in addition a DNA construction where a reporter gene is ligated at the downstream area of a promoter having a responsive element of a transcription factor, which is the a Gal4- responsive promoter linked to a reporter gene which is a c-fos gene or a CAT gene (see Fig. 1 and page 1658). The reference teaches that the disclosed expression control system may be used in other tissue culture cells (see page 1657, second column, second complete paragraph). The difference between the reference and the instant claims is that the cell in which the constructs are present is the Namalwa KJM-1 cell which is adapted for serum-free culture, and the reporter gene is firefly luciferase gene.

However, Miyaji et al. disclose Namalwa KJM-1 cells adapted for serum-free culture, and disclose the usefulness of said cells for foreign gene expression (see page 173). It is noted that DNA encoding Gα proteins are present in all mammalian, or human, or specifically, a B cell line. Scheirer discloses lymphoblastoid cells comprising DNA constructs comprising a promoter linked to the luciferase reporter gene (see col. 8).

It would have been obvious to one of ordinary skill in the art to have utilized the cells disclosed by Miyaji et al. as the host cell for the expression system disclosed by Braselmann et al., since Miyaji et al. and Braselmann each are concerned with the expression of foreign genes in tissue culture cells of interest. One would have been motivated to do so by the disclose of Braselmann et al. of the usefulness of the disclosed expression system for control of expression of genes in any tissue culture cell of interest, and in view of the usefulness of the KJM-1 Namalwa cells for expression of foreign genes and production of proteins of interest. It would have been further obvious to one of ordinary skill in the art to have utilized a well known reporter gene such as luciferase gene disclosed by Scheirer in the constructs disclosed by Braselmann and Miyaji et al., since luciferase is known to be a useful reporter gene, and in the absence of unexpected results, the substitution of one reporter gene for another would have been obvious to one of ordinary skill in the art. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 75, 77, 109, are rejected under 35 U.S.C. 103(a) as being unpatentable over Braselmann et al. . (Proc. Natl. Acad. Sci. USA 90:1657-1661, 1993) in view of Miyaji et al. (Cytotechnology, 4(2):173-180, 1990), and Scheirer (US Patent 5,866,342) and Brown et al. (US Patent 6,509,447) and Milligan et al. (Trends Pharmacol. Sci. (1999) 20:118-124).

Braselmann et al. disclose a mammalian cell comprising a DNA construct for expression of a transcription factor necessary for construction of an inducible expression system, wherein the transcription factor is a chimeric protein of a ligand binding domain of estrogen receptor and yeast Gal4p. Braselmann et al. disclose cells comprising in addition a DNA construction where a reporter gene is ligated at the downstream area of a promoter having a responsive element of a transcription factor, which is the a Gal4- responsive promoter linked to a reporter gene which is a c-fos gene or a CAT gene (see Fig. 1 and page 1658). The reference teaches that the disclosed expression control system may be used in other tissue culture cells (see page 1657, second column, second complete paragraph). The difference between the reference and the instant claims is that the cell in which the constructs are present is the Namalwa KJM-1 cell which is adapted for serum-free culture, and the reporter gene is firefly luciferase gene, and a chimeric G protein in which the 5 C-terminal amino acids of Galphas or Galphaq are substituted with those from other G alpha proteins.

However, Miyaji et al. disclose Namalwa KJM-1 cells adapted for serum-free culture, and disclose the usefulness of said cells for foreign gene expression (see page

173). It is noted that DNA encoding Gα proteins are present in all mammalian, or human, or specifically, a B cell line. Scheirer discloses lymphoblastoid cells comprising DNA constructs comprising a promoter linked to the luciferase reporter gene (see col. 8). Brown et al. disclose chimeric G alpha proteins having the 5 C-terminal amino acids substituted with corresponding amino acids from other Galpha proteins (see col. 3). Brown et al,. and Milligan et al. teach that chimeric Galpha proteins having the C-terminal 5 amino acids substituted with other corresponding amino acids from other G alpha proteins are useful in screening assays.

It would have been obvious to one of ordinary skill in the art to have utilized the cells disclosed by Miyaji et al. as the host cell for the expression system disclosed by Braselmann et al., since Miyaji et al. and Braselmann each are concerned with the expression of foreign genes in tissue culture cells of interest. One would have been motivated to do so by the disclose of Braselmann et al. of the usefulness of the disclosed expression system for control of expression of genes in any tissue culture cell of interest, and in view of the usefulness of the KJM-1 Namalwa cells for expression of foreign genes and production of proteins of interest. It would have been further obvious to one of ordinary skill in the art to have utilized a well known reporter gene such as luciferase gene disclosed by Scheirer in the constructs disclosed by Braselmann and Miyaji et al., since luciferase is known to be a useful reporter gene, and in the absence of unexpected results, the substitution of one reporter gene for another would have been obvious to one of ordinary skill in the art. It would have been further obvious to have utilized any chimeric Galpha proteins, since Brown et al. and Milligan et al. teach

that they are useful in screening assays due to improved function. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
3/15/09

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